



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-23-23DV; Docket No. CDC-2023-0023]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Focus groups among adults with or caring for individuals with congenital heart defects (CHD), muscular dystrophy (MD), and spina bifida (SB). The purpose of this project is to conduct focus groups to obtain firsthand perspectives from individuals with CHD, MD, and SB.

**DATES:** CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2023-0023 by either of the following methods:

- Federal eRulemaking Portal: [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [www.regulations.gov](http://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([www.regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Focus groups among adults with or caring for individuals with congenital heart defects (CHD), muscular dystrophy (MD), and spina bifida (SB) - New - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Congenital Heart Defects (CHD) are the most common type of structural birth defects in the United States, affecting approximately one in 110 live-born children, and are a leading cause of birth defect-associated infant mortality, morbidity, and healthcare costs. Due to advances in diagnosis and medical interventions, CHD mortality has decreased over the past few decades. Therefore, more individuals are living into adulthood with CHD, a lifelong condition, that can increase the need for specialist care and clinical interventions due to the higher risk of CHD related long-term sequelae.

There is limited data on adults living with CHD who have fallen out of cardiac care, and the available information is strictly among those who returned to care. Currently, there is no information on adults with CHD who remain out of care and what might bring them back into cardiac care. Understanding what may bring adults with CHD back into care, aside from an urgent cardiac need, would help in developing interventions, as well as improving access and retention to cardiac care, ultimately improving long-term health and wellbeing.

Focus group participants with CHD will be recruited from adults that participated in the Congenital Heart Survey to Recognize Outcomes, Needs and well-being (CH STRONG). Between 2016 and 2019, CH STRONG was administered to adults ages 19-38 with a confirmed CHD diagnosis, born in Arizona, Arkansas, and 5-county Metro- Atlanta, Georgia. CH STRONG assessed many factors, including access to care and healthcare utilization. Through survey responses we will identify a subpopulation of respondents whose last cardiology encounter was  $\geq 3$  years before survey completion, creating a unique opportunity to better understand this population not typically available to researchers.

Muscular Dystrophies (MD) are a group of rare inherited disorders characterized by progressive and irreversible muscle weakness and wasting. The nine major types of MD (Duchenne and Becker [DBMD], myotonic dystrophy [DM], congenital [CMD], limb girdle [LGMD], Emory-Dreifuss [EDMD], facioscapulohumeral [FSHD], distal, and oculopharyngeal [OPMD]) vary by age of onset, muscle groups affected, genes involved, severity, and progression of disease. In 2002, CDC implemented the Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet [DD-19-002]). Now in its fourth funding cycle, MDSTARnet has conducted surveillance and collected epidemiologic and clinical data on people with DBMD, DM, FSHD, LGMD, CMD, OPMD, EDMD, and distal MD and has published numerous articles in scientific journals. However, qualitative data on the

experiences of individuals with certain types of MD (DBMD, DM, FSHD, LGMD, and CMD) or their caregivers are limited. The MD portion of this collection will focus on gathering qualitative information to better understand the personal experiences of adults ( $\geq 18$  years) with DBMD, FSHD, DM, and LGMD as well as adult caregivers of youth ( $< 18$  years) with DBMD, congenital or juvenile onset DM, and CMD. Specifically, qualitative data on barriers to accessing and receiving care, the journey to diagnosis, and for those diagnosed early in life the transition into adulthood will help to address a gap in the literature and inform future research and surveillance efforts.

Spina bifida (SB) is among the most common disabling birth defects in the United States. Based on national data from 2010-2014, the estimated birth prevalence for spina bifida is 3.9 per 10,000 live births. SB impacts different organ systems, resulting in the need for various types of clinical specialists. In 2008, CDC implemented the National Spina Bifida Patient Registry (NSBPR; [DD-19-001]) with SB clinics across the United States. In 2014, CDC funded a subset of NSBPR clinics to establish and implement the "Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida" (UMPIRE Protocol; [DD-14-002]). NSBPR and UMPIRE have generated numerous publications on clinical interventions, health outcomes, and lessons learned. However, increases in survival for individuals with SB have prompted the need for greater understanding of the complexities involved in their

clinical and psychological care. Qualitative data on individual and caregiver experiences with SB, including barriers to accessing specialty care, managing one's skin health and bowel and bladder function, and the transition from childhood to adulthood (for those with MD diagnosed prior to adulthood) are needed to guide future SB surveillance and research projects as well as the care of those aging into adulthood.

The purpose of this project is to conduct virtual focus groups among adults with or caring for individuals with CHD, MD, and SB with a special focus on: receipt of and access to medical care (including specialist care), and barriers and facilitators to accessing, receiving, or reengaging care; the journey to diagnosis; and the transition period from pediatric to adult care (for persons diagnosed during childhood). This information may be used to address gaps in knowledge, inform future surveillance, research, and data collection, and gather patient perspectives that may be shared with clinicians and inform clinical care.

CDC requests OMB approval for an estimated 533 annual burden hours. There is no cost to respondents other than their time to participate.

#### Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Adults	CHD Screening	410	1	10/60	68

with a CHD that have been out of cardiac care for $\geq 3$ .	Questionnaire				
Adults with a CHD that have been out of cardiac care for $\geq 3$ .	CHD Focus Group Guide	80	1	90/60	120
Adults with MD or adult caregivers of individuals with MD	MD Screening Tool	215	1	10/60	36
Adults with MD or adult caregivers of individuals with MD	MD Focus Group Guide	135	1	90/60	203
Adults with SB or adult caregivers of individuals with SB	SB Screening Tool	95	1	10/60	16
Adults with SB or adult caregivers of individuals with SB	SB Focus Group Guide	60	1	90/60	90
Total					533



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